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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,127	04/08/2004	Michael D. Laufer	100873-266 (END6430USCNT4)	8654
81353 7590 05/11/2009 Ethicon Endo-Surgery/Nutter, McClennen & Fish LLP World Trade Center West 155 Seaport Blvd. Boston, MA 02210-2604			EXAMINER WOO, JULIAN W	
			ART UNIT 3773	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/820,127	Applicant(s) LAUFER ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/13/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 24-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 24-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/20/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 45, and 49-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilk (5,395,367). Wilk discloses as claimed, at least in figures 10-12c and in col. 11, line 41 to col. 12 line 33; a tissue shaping instrument or apparatus including a proximal controlling portion (at the vicinity of 118) structured to actuate the tissue engaging devices (i.e., the controlling portion accommodates actuators for the devices), a distal effector portion (at the vicinity of 116), an elongated member (114), and a first tissue engaging device (e.g., 120) and a second tissue engaging device (e.g., 122), where the second tissue engaging device is movable relative to the first tissue engaging device and hingedly pivotable relative to a long axis of the elongated member (at the pivot between 136a or 136b and 134 and/or between 136a and 138 or between 136b and 140), where the instrument is an endoscopic instrument, where the instrument includes a tissue securing device (e.g., 126 or 130), where the instrument includes first and second actuating mechanisms (e.g., 124 and 128, respectively).

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3. Claims 24, 25, 27, 29-34, and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Yoon (5,954,731). Yoon discloses, at least in figures 1-3b, 5, and 7-8 and in col. 10, line 15 to col. 13, line 14; col. 13, line 30 to col. 14, line 3; and col. 18, lines 28-45; an apparatus comprising means for engaging a plurality of stomach tissue regions with a plurality of members (e.g., 18a and 18b) from within the stomach or first and second movable members, at least one of the members configured to move toward another member (see figs. 7-7C), where the plurality of members includes a first member having a first securing part (e.g., 111a), a second member having a second securing part (111b), the means for engaging including an actuating mechanism (14) operatively linking the first and second members to facilitate simultaneous independent movement of the members to draw together the first and second stomach tissue sections, and means for pulling tissue located between the plurality of regions of tissue prior to engaging the plurality of regions of tissue (190) or means for securing reconfigured tissue, where the first and second securing parts comprise tissue engaging means, a clamping device, or a grasping device; where the securing means includes a biocompatible, non-resorbable clip (see fig. 8); and where the first and second members are positioned at different locations on a long-axis of the elongated member (see col. 11, lines 18-30).

4. Claims 34, 35, 37, and 39-44 are rejected under 35 U.S.C. 102(e) as anticipated by Kuehn et al. (6,695,866). Kuehn et al. disclose, at least in figures 16, 17, and 19A-19D and in col. 9, lines 2-12; an apparatus comprising a substantially rigid (i.e., somewhat flexible) elongated member (108) configured for transoral placement in the

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stomach, where the elongated member having a steerable distal region including first and second movable members (at 404) configured to be moved toward one another, and means for deploying an implant from at least one of the members (404), where the first movable member includes a first securing part (424) and the second movable member includes a second securing part (426), where the elongated member includes a clamping device or a grasping device (402), where the deploying means includes a distal end effector (402) configured to contact reconfigured stomach tissue, where the distal end effector includes a tissue fixation device (424, 426) configured for the application of a tissue fixation device, where the apparatus includes means for controlling the distal end effector at a proximal end of the apparatus (432) and operatively connected to the distal end effector, and where the first and second movable members are positioned at different locations on a long-axis of the elongated member (e.g., element 404 can be “withdrawn,” while element 402 grabs tissue).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 5-7, 9, 17, 18, 20 are rejected under 35 U.S.C. 102(b) as anticipated by Wilk (5,395,367) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wilk (5,395,367). Under 35 U.S.C. 102(b), Wilk discloses, at least in figures 7 and in col. 9, line 44 to col. 10, line 55, a tissue shaping instrument including an elongated member having an inner tubular member (e.g., sheath of 35 or 36) and an outer tubular member (32) concentrically disposed around the inner tubular member, a proximal controlling portion (actuators and port at the vicinity of 38), a first tissue engaging device (e.g., 35 or 36) disposed on the inner tubular member (i.e., the shaft of 36 is in contact with the sheath of 35), a second tissue engaging device (e.g., 34) disposed on the inner tubular member (i.e., the shaft of 34 is in contact with the sheath of 35), or elements 38 of engaging devices are disposed on outer tubular member 32; and a tissue securing device (e.g., 35), where the first tissue engaging device (36) includes a jawed clamp, where the tissue securing device comprises a stapler (see col. 10, lines 31-35), where the second tissue engaging device comprises opposed articulable arms (34a) with a tissue piercing element (pointed tips of 34a) disposed at a distal end of each arm, where the first tissue engaging device is non-piercing (e.g., 36a), where the instrument includes at least one working channel (within 32), where at least part of the elongated member is flexible (e.g., 36e), where the instrument includes a tissue grasper (e.g., 35 or 36) disposed on a distal end of the articulable arm opposite the tissue piercing element (i.e., positioned adjacent the distal end of the articulable arms when shafts are

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in parallel), and where the instrument includes a suction device (not shown) disposed on a distal end of the articulable arm opposite the tissue piercing element (i.e., positioned adjacent the distal end of the articulable arms when shafts are in parallel).

Alternatively, under 35 U.S.C. 103, Wilk discloses the tissue shaping instrument substantially as claimed. Wilk discloses, inter alia, in fig. 7 and col. 9, lines 43-55; a tissue shaping instrument comprising an elongated member (a "trocar sleeve" or "laparoscopic cannula" and element 32 combined) including an inner tubular member (32) and an outer tubular member (a "trocar sleeve" or "laparoscopic cannula") concentrically disposed around the inner tubular member, where the instrument includes a proximal controlling portion first and second tissue engaging devices (e.g., 34, 35, and 36). However, Wilk does not explicitly disclose that the engaging devices are each disposed on one of the inner and the outer tubular members. Nevertheless, Wilk teaches, in fig. 4, tissue engaging devices (354 and 356) disposable on a tubular member (344), where portions of the devices (at 350 and 352) may contact the proximal portion element 344, if the devices are inserted further into the tubular member. Similarly, Wilk teaches, in figs. 12A-12C, a tissue shaping instrument with an inner tubular member (114) and an outer tubular member (144), where tissue engaging devices (120, 122) contact the inner tubular member (at 118) or may contact the proximal portion of the outer tubular member (i.e., elements 124 and 128 of the engaging devices are disposable on the outer tubular member, if the devices are inserted further into the outer tubular member). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Wilk's

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teachings, to dispose the first and second tissue engaging devices on the proximal surface of one of the inner tubular member and the outer tubular member. Such a configuration would safely prevent the engaging devices from being inserted too far or dropped through a tubular member, and it would allow the actuators of the engaging devices to remain outside of a patient's body for convenient access to the devices by a user.

7. Claims 4, 10-13, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of McGarry et al. (5,289,963). Wilk discloses the invention substantially as claimed. Wilk discloses a stapler as one of the tissue engaging devices or as a tissue securing device. However, Wilk does not disclose a tissue fixation device that is a staple and a stapler that is a one-sided stapler; nor does Wilk disclose that the instrument is sterilized. McGarry et al. teach, at least in figures 1 and 17-28 and in col. 10, lines 30-40 and col. 17, line 36 to col. 19, line 36; a tissue fixation device that is a staple delivered from a one-sided stapler, where the stapler is sterilized. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of McGarry et al., to apply a one-sided stapler and a staple in the instrument of Wilk. Such devices would allow the endoscopic fastening of tissue, where the surgical site has narrow confines. It would also be obvious to sterilize the instrument, so that the instrument would not infect or contaminate the surgical site.

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8. Claims 8 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of McPherson et al. (5,437,266). Wilk discloses the invention substantially as claimed, but does not disclose an engaging device that comprises a corkscrew-like retractor or tissue piercing elements at the distal end of the each of articulable arms (i.e., positioned adjacent to the distal ends of the arms), where the tissue piercing elements include a coil with a sharp distal tip. McPherson et al. teach a corkscrew-like retractor or a coil with a sharp distal tip. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of McPherson et al., to apply a corkscrew-like retractor or a corkscrew element or a coil with a sharp distal tip in the instrument of Wilk. Such a device would allow the secure, endoscopic fastening of tissue being manipulated or retracted during a surgical procedure.

9. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (5,954,731) in view of McPherson et al. (5,437,266). Yoon discloses the invention substantially as claimed. Yoon discloses, in col. 6, lines 52-59, various tissue engaging means, but does not disclose a corkscrew element or an elongated member including the corkscrew element. McPherson et al. teach a corkscrew element. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of McPherson et al., to apply a corkscrew element in the apparatus of Yoon. Such a device would allow the secure, endoscopic fastening of tissue being manipulated or retracted during a surgical procedure.

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10. Claims 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of McPherson et al. (5,437,266). Wilk discloses the invention substantially as claimed, where the apparatus includes an elongated member (32 and/or 34b, 35b, 36b) with a steerable distal region (at 34b, 35b, or 36b) and a means for deploying an implant (e.g., a stapler or suture applicator (not shown)), where the elongated member includes a suction device (not shown). However, Wilk does not disclose an engaging device or means that comprises a corkscrew-like retractor or a corkscrew element or an elongated member including the corkscrew element, nor does Wilk disclose tissue piercing elements at the distal end of the each of articulable arms (i.e., positioned adjacent to the distal ends of the arms), where the tissue piercing elements include a coil with a sharp distal tip. McPherson et al. teach a corkscrew-like retractor or a corkscrew element or a coil with sharp distal tip. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of McPherson et al., to apply a corkscrew-like retractor or a corkscrew element or a coil with a sharp distal tip in the instrument of Wilk. Such a device would allow the secure, endoscopic fastening of tissue being manipulated or retracted during a surgical procedure.

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of Kuehn et al. (6,695,866). Wilk discloses the invention substantially as claimed, but does not disclose a tissue fixation device that is a two-part fastener. Kuehn et al. teach, at least in figures 17 and 19A-19D, a tissue fixation device that is a two-part fastener (424, 426). It would have been obvious to one having

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ordinary skill in the art at the time the invention was made, in view of Kuehn et al., to apply a tissue fixation device that is a two-part fastener in the instrument of Wilk. Such a fastener would allow the secure fastening of tissue with little risk of separation of joined tissues.

12. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of Kammerer et al. (6,152,935). Wilk discloses the invention substantially as claimed, but does not disclose a tissue fixation device that is a suture or a T-bar suture. Kammerer et al. teach, at least in the figures, a suture or a T-bar suture (e.g., 30). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kammerer et al., to apply a tissue fixation device that is a suture or a T-bar suture in the instrument of Wilk. Such a fastener would allow the endoscopic fastening or approximation of tissues during a minimally-invasive surgical procedure.

13. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of Yoon (5,954,731). Wilk discloses the invention substantially as claimed, but does not disclose that instrument includes a viewing endoscope. Yoon teaches, at least in figure 4, an instrument with tissue engaging devices and a viewing endoscope (26). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Yoon, to include a viewing endoscope in the instrument of Wilk. Such a device would allow a surgeon to directly view a surgical site during a procedure and allow the surgeon to precisely manipulate the instrument within the surgical site.

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14. Claims 28 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (5,954,731) in view of Wilk (5,395,367). Yoon discloses the invention substantially as claimed. Yoon discloses, in col. 13, lines 15-21, an apparatus including channels 22a-22e usable for aspiration, but Yoon does not disclose a tissue engaging means including a suction device. Wilk teaches, in col. 10, lines 28-35, an apparatus including a tissue engaging means that is a suction device. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Wilk, to include a suction device with the apparatus of Yoon. Such a modification would allow direct aspiration of a surgical site or the holding of tissue for suturing.

15. Claims 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,395,367) in view of Iacovelli (5,350,391). Wilk disclose the invention substantially as claimed, but does not disclose that the first actuating mechanism includes a control cable cooperating with a biasing member or a second actuating mechanism including a biasing member acting between the articulable arms and a pair of control cables cooperating with the biasing member. Iacovelli teaches, at least in figures 1-16 and col. 6, lines 42-64; an actuating mechanism for forceps or scissors, where the mechanism includes a biasing member (a torsion spring—not shown) acting between articulable arms (54) and cooperating with a pair of control cables (64). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Iacovelli, to include a biasing member and control cables with the first and/or second actuating mechanisms of Wilk. A biasing member would urge the opening of the articulable arms, so that tissue or other objects may be grasped between

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the arms, while control cables would allow actuation of the arms via the narrow, endoscopic shaft of the instrument.

Response to Amendment

16. Applicant's arguments filed on February 13, 2009 and regarding the rejections of claims 1-20, 35-37, and 39-52 based on Wilk and Kuehn have been fully considered but are not persuasive or are moot in view of new grounds of rejection. With respect to arguments regarding base claim 1 and the Wilk reference: Wilk indeed discloses, in figures 10-12c, a structure (136) that enables tissue engaging members to be hingedly pivotable relative to the long-axis of the elongated member, where the pivotable connections provided by the structure are distinct from bending points of the shafts of the engaging members. With respect to the rejection of base claim 5, the Wilk reference was reconsidered, and the Examiner determined that Wilk's teachings regarding tissue shaping instruments either anticipate or are obvious over the Applicant's claims. Applicant should further note that the Examiner has given "concentrically" its broadest reasonable interpretation, where the ENCARTA World English Dictionary defines "concentric" to be:

- 1. with common middle point:** describes circles and spheres of different sizes with the same middle point
- 2. with common axis:** with a common axis or center line

With respect to the first definition, the sheaths of elements 34, 35, and 36 can be said to share a common middle point with element 32. That is, a middle point between the axes of the sheaths (inner tubular members) is common with the axis of element 32 (outer tubular member). Alternatively, with respect to the second definition, element

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144 (outer tubular member in this case) can be said to have a common axis with element 32 (the inner tubular member in this case).

With respect to arguments regarding the rejection based on Kuehn, the first and second movable members are movable relative to each other within the elongated member, so they are positionable at different locations on or along a long-axis of the elongated member.

Applicant's arguments regarding the rejection of claims 5-7, 9, 17, 18, 20, 24-34, 38, and 53 have been fully considered but are moot in view of new grounds of rejection.

The rejection of claims 26 and 28 based on 35 U.S.C. 112 is hereby withdrawn.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773